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| 09/939,230 | 08/24/2001 | Alan David Wickenden | 018512-006610US | 5203 |

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EXAMINER

JONES, DWAYNE C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1614

DATE MAILED: 09/26/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,230

Applicant(s)

WICKENDEN ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on the election response of 04 MAR 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) 1-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1-82 are pending.
2. Claims 45-82 are elected and rejected.
3. Claims 1-44 are non-elected and withdrawn from consideration.

Election/Restrictions

4. Applicant's election with traverse of Group II in Paper No. 3 is acknowledged.
The traversal is on the ground(s) that Groups I and II are not separate and distinct. This is not found persuasive because the inventions of Groups I and II do possess different functions and effects
5. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 45-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient descriptive support for the

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phrase, "a compound able to increase ion flow through KCNQ potassium channels". In addition, the instant specification does not describe what is meant by the phrase, "a compound able to increase ion flow through KCNQ potassium channels" other than the N-aryl benzylamide compounds of Figure 7. Structural identifying characteristics of the phrase, "a compound able to increase ion flow through KCNQ potassium channels" are not disclosed except for those the N-aryl benzylamide compounds of Figure 7. There is no evidence that there is any per se structure/function relationship between the phrase, "a compound able to increase ion flow through KCNQ potassium channels" other than those disclosed, namely the N-aryl benzylamide compounds of Figure 7. The instant specification does provide an adequate written description for the phrase, "a compound able to increase ion flow through KCNQ potassium channels". Accordingly, these claims fail to comply with the written description requirement.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 45-48, 54-59, 61-65, 70, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaster et al. of U.S. Patent No. 6,235,758. Gaster et al. teach of aryl carbamoyl compounds that are used to treat anxiety, (see column 1 and compound Nos. 1-177). Gaster et al. do not specifically teach of KNCQ potassium channels. Gaster et al. also teach of pharmaceutical modes of administration and dosages, (see column 9, lines 28-46 and column 10, lines 8-20). It is further noted that the courts have held that, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art.", *In re Swinehart*, 169 USPQ 226. In addition, it seems that applicants' invention have further elucidated the biochemical mechanism of opening the KNCQ potassium channels with the aryl carbamoyl compounds that are used to treat anxiety. Accordingly, it would have

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been obvious to one having ordinary skill in the art to treat the very same ailment of anxiety as is instantly claimed because applicants' invention are simply claiming a biochemical mechanistic step that is already inherent with the administration of the aryl carbamoyl compounds of the prior art reference of Gaster et al. The skilled artisan would have been motivated to select the compounds of Gaster et al. to treat the very same ailment with the expectation that the prior art compounds would inherently possess the same biochemical properties and effects, namely opening of the KNCQ potassium channel.

Obviousness-type Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 45-57 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46-67 of McNaughton-Smith et al. of U.S. Patent No. 6,593,349. Although the conflicting claims are not identical, they are not patentably distinct from each other because McNaughton-Smith et al. teach of the

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KCNQ potassium channel opener compounds. In addition, McNaughton-Smith et al. disclose that these KCNQ potassium channel opener compounds can be administered orally or by injection in various amounts, (see columns 19-21). McNaughton-Smith et al. also disclose that the KCNQ potassium channels may include homomultimers and heteromultimers of inter alia KCNQ2 and KCNQ3, (see column 22, lines 40-58).

14. Claims 45-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46-67 of McNaughton-Smith et al. of U.S. Patent No. 6,593,349 Gaster et al. of U.S. Patent No. 6,235,758. Although the conflicting claims are not identical, they are not patentably distinct from each other because McNaughton-Smith et al. teach of the KCNQ potassium channel opener compounds. In addition, McNaughton-Smith et al. disclose that these KCNQ potassium channel opener compounds can be administered orally or by injection in various amounts, (see columns 19-21). McNaughton-Smith et al. also disclose that the KCNQ potassium channels may include homomultimers and heteromultimers of inter alia KCNQ2 and KCNQ3, (see column 22, lines 40-58). Gaster et al. do not specifically teach of KNCQ potassium channels. Gaster et al. also teach of pharmaceutical modes of administration and dosages, (see column 9, lines 28-46 and column 10, lines 8-20). In addition, Gaster et al. also teach of the administration of carbamoyl compounds for the treatment of anxiety. Clearly, it would have been obvious to the skilled artisan to utilize the carbamoyl compounds of Gaster et al. with the expectation of opening KNCQ potassium channels because both of these prior art references teach of treating anxiety with carbamoyl compounds, as is instantly claimed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


D. C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
September 20, 2003